



UNITED STATES PATENT AND TRADEMARK OFFICE

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FEB 28 2012

Christine S. Lee  
Intellectual Property Counsel  
GE Healthcare  
101 Carnegie Center  
Princeton, NJ 08540

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,310,912

Dear Ms. Lee:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,310,912 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:  
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>  
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).

Mary C. Till  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

RE: DaTscan (Ioflupane I-123)  
Docket No.: FDA-2011-E-0367

Attention: Beverly Friedman

**UNITED STATES PATENT AND TRADEMARK OFFICE**

In re GE Healthcare Ltd. :  
Request for Patent Term Extension : ORDER GRANTING  
U.S. Patent No. 5,310,912 : INTERIM EXTENSION

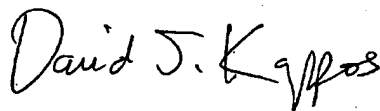
GE Healthcare Ltd., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,310,912, filed an application for patent term extension under 35 U.S.C. § 156 on March 7, 2011. The original term of the patent is due to expire on February 25, 2012. The patent claims the active ingredient ioflupane, in the human drug product DaTscan®, which was approved by the Food and Drug Administration for commercial marketing or use on January 14, 2011. An extension of 5 years is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,310,912 is granted for a period of one year from the original expiration date of the patent.

February 24, 2012

Date



David J. Kappos  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office